MAR 14 2012 K120074

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510(k) Summary

Date:	6 January 2012
Sponsor:	The Skeletal Design Partnership Ltd The Conifers, Filton Road Hambrook Bristol BS16 1QG United Kingdom Phone: 44 1275 376 987 Fax: 44 117 327 0292
Contact Person:	Alan Rorke, Director
Proposed Trade Name:	Foundation Spinal System
Device Classification	Class III, Class II and Class II
Classification Name:	Pedicle screw spinal system, Spinal interlaminal fixation orthosis and Spinal intervertebral body fixation orthosis
Common Name:	Spinal fixation system
Regulation:	888.3070, 888.3050 and 888.3060
Device Product Codes:	NKB/MNI/MNH, KWP and KWQ
Device Description:	The Foundation Spinal System consists of rods, hooks, staple plates, monoaxial and multiaxial screws with set screws and crosslinks with fastening set screws. Rods are available either straight or pre-contoured in a variety of lengths. Hooks and staple plates are offered in a variety of sizes. Solid and cannulated screws are available in standard and reduction versions in a variety of diameter-length combinations to accommodate differing patient anatomy.
Intended Use:	The Foundation Spinal System is intended for thoracolumbar (T4-L4) anterolateral screw fixation and posterior, non-cervical (T1-S1) pedicle and non-pedicle fixation to provide immobilization and stabilization in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion.
Materials:	The Foundation Spinal System components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.

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Predicate Devices: Kaneda SR Spinal System (K971248)
CD HORIZON® (K031655/K041460),
Expedium™ 5.5 Ti Spine System (K041119/K051024)
Moss® Miami (K992168/K022623) and the
Synergy™ VLS (K950099/K974749)

Technological Characteristics: The Foundation Spinal System possesses the same technological characteristics as the predicates. These include

- basic design (rod-based fixation system having monoaxial and multiaxial screws and various hook and staple plate sizes),
- material (titanium alloy),
- sizes (rod and screw sizes are encompassed by those offered by the predicate systems) and
- intended use (as described above).

The fundamental scientific technology of the Foundation Spinal System is the same as the previously cleared device.

Performance Data: Static compression bending and torsion, and dynamic compression bending of the worst case Foundation construct was performed according to ASTM F1717. The mechanical test results demonstrated that the Foundation Spinal System performs as well as or better than the predicate devices.

Conclusion: In comparison to the predicate devices, the Foundation Spinal System has

- the same intended use (as described above),
- the same technological characteristics (as described above)

and so does not raise new questions of safety and effectiveness.

Therefore the Foundation Spinal System can be found substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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The Skeletal Design Partnership Ltd.
% BackRoads Consulting Inc.
Karen E. Warden, Ph.D.
8202 Sherman Road
Chesterland, Ohio 44026-2141

Re: K120074
Trade/Device Name: Foundation Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: January 6, 2012
Received: January 10, 2012

Dear Dr Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number: K120074

Device Name: **Foundation Spinal System**

Indications for Use:

The Foundation Spinal System is intended for thoracolumbar (T4-L4) anterolateral screw fixation and posterior, non-cervical (T1-S1) pedicle and non-pedicle fixation to provide immobilization and stabilization in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion.

Prescription Use X AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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